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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/774,282	01/29/2001	James M. Lipton	257/019	2528

34055 7590 09/05/2003

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EXAMINER	
LANDSMAN, ROBERT S	

ART UNIT	PAPER NUMBER
1647	13

DATE MAILED: 09/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/774,282	LIPTON ET AL.	
	Examiner	Art Unit	
	Robert Landsman	1647	

-- The MAILING DATE of this communication appears on the cover sh t with the corresp ndence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) 1-28 is/are pending in the application.

4a) Of the above claim(s) 20-28 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-19 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,10,11 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Formal Matters

A. Amendment A, filed 6/13/03, has been entered into the record.

B. The Information Disclosure Statement, filed 3/20/03, has been entered into the record.

C. The Information Disclosure Statement, filed 3/14/03, has been entered into the record.

D. The Information Disclosure Statement, filed 2/20/03, has been entered into the record.

E. Claims 1-28 are pending in the application and were subject to restriction in Paper No. 6, dated 10/07/02. In Paper No. 7, filed 2/7/03, Applicants elected Group I, claims 1-19, with traverse. In view of Applicants' arguments, all Groups will be combined and searched.

2. Information Disclosure Statement

A. References AA and AD-AG on the IDS filed 2/20/02 have been lined through since US applications are not proper subject matter for an IDS. If these references are considered on a Form 1449, they will become public information. If these application are solely those of the present inventors and Applicants want these reference to be printed, they are urged to resubmit these references on a new Form 1449 and state that the inventors on the cited applications are the same and only include the inventors of the present invention.

3. Claim Rejections - 35 USC § 112, first paragraph – enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. Claims 1-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for pharmaceutical compositions using fragments of MSH ending in KPV, including SEQ ID NO:3, 4 and 8 and methods for treating candidiasis, does not reasonably provide enablement for pharmaceutical compositions comprising any and all proteins which have a C-terminal sequence KPV or for methods of treating all oral pathologies. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

First, the breadth of the claims is excessive with regard to claiming pharmaceutical compositions comprising any and all proteins which have a C-terminal sequence KPV or for methods of treating all oral pathologies Applicants have only provided guidance and working examples of the use of SEQ ID NO:1, 3, 4 and 8 in the treatment of oral candidaisis produced by C. albicans (Figures 1 and 2). Applicants have provided no guidance or working examples of any other pharmaceutical composition comprising any other protein with a C-terminal KPV sequence other than those found in α-MSH, for this purpose, nor have Applicants provided any guidance or working examples of the treatment of any other pathology other than candidaisis produced from C. albicans. In absence of evidence to the contrary, it would not be expected that any and all pharmaceutical composition comprising a C-terminal KPV sequence would be expected to treat any and all oral fungal pathologies. Furthermore, it would not be predictable to the artisan which proteins comprising a KPV C-terminal sequence would work in the present invention, nor would it be predictable to the artisan which oral fungal pathologies could be treated with these compositions.

Therefore, in summary, the breadth of the claims is excessive with regard to Applicants claiming pharmaceutical compositions comprising any and all proteins which have a C-terminal sequence KPV or for methods of treating all oral pathologies other than candidaisis produced by C. albicans. There is also only minimal guidance and working examples of these KPV-terminal proteins and no guidance or working examples of pathologies other than candidaisis produced by C. albicans. These factors, along with the lack of predictability to one of ordinary skill in the art as to how to make a pharmaceutical composition other than those of SEQ ID NO:1, 3, 4 and 8 which are not part of α-MSH, and how to use these compositions to treat oral pathologies other than candidaisis produced by C. albicans, leads the Examiner to hold that undue experimentation is necessary to practice the invention as claimed.

4. Claim Rejections - 35 USC § 112, first paragraph – written description

A. Claims 1-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These are genus claims. Applicants are claiming pharmaceutical compositions comprising any and all proteins which have a C-terminal sequence KPV or for methods of treating all oral pathologies. Proteins comprising a C-terminal KPV sequence other than those found in MSH would have one or more amino acid substitutions, deletions, insertions and/or additions to MSH. The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus, other than the inclusion of a KPV C-terminal sequence. Thus the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. The specification and claims do not provide any guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure. No common structural attributes identify the members of the genus other than that they must comprise KPV and treat an oral pathology. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, a C-terminal KPV sequence, as well as "fungal pathologies of the oral cavity," alone are insufficient to describe the genus. One of skill in the art would reasonable conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus at the time the invention was made.

5. Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

A. Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Catania et al. (US 2002/0137685) in view of Applicants' specification. The claims recite pharmaceutical compositions for the treatment of fungal pathologies by administering a peptide with a KPV C-terminal sequence along with a fungicide and, optionally, an antibiotic. The claims also recite methods of using these compositions in the treatment of said pathologies. Catania et al. teach the use of "KPV" compounds in the treatment of the fungal pathology produced by C. albicans (Abstract) as well as methods of using these compounds to treat these pathologies (inherent from entire document – see especially page 5, paragraph [0074]). The claims do not recite the use of a fungicide. However, it would have been obvious to one of ordinary skill in the art to have included a fungicide since C. albicans is a fungus. It would also have been obvious to use antibiotics in combination with fungicide treatment to avoid or treat any secondary infections (page 1 of the specification).

B. Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mahe et al. (WO 97/10838 - reference DX on the IDS dated 3/14/03). The teachings of the claims are seen above. Mahe et al. teach the use of "KPV" compounds in the treatment of inflammation (Abstract) as well as methods of using these compounds to treat inflammation (inherent from entire document). Mahe et al. do not teach the use of this compound in conjunction with a fungicide. However, the administration of the compound of Mahe even without the fungicide would inherently have the same effect in treating a fungal infection. The fungicide would be expected to have additive effects, but the methods of the claimed invention would still be achieved in the absence of the fungicide. It would also have been obvious to use antibiotics in combination with fungicide treatment to avoid or treat any secondary infections (page 1 of the specification).

C. Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Csato et al. (reference BJ on the IDS submitted 2/20/00) in view of Applicants' specification. The claims are taught above. Csato et al. teach the use of "KPV" compounds in the treatment of the fungal pathology produced by C. albicans (entire document, especially paragraph 3 on page 145). The claims do not recite the use of a fungicide. However, it would have been obvious to one of ordinary skill in the art to have included a fungicide since C. albicans is a fungus. It would also have been obvious to use antibiotics in combination with fungicide treatment to avoid or treat any secondary infections (page 1 of the specification).

D. Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipton et al. (reference EF on the IDS dated 3/14/03). The teachings of the claims are seen above. Lipton et al. teach the use of "KPV" compounds in the treatment of inflammation (Abstract) as well as methods of using these compounds to treat inflammation (inherent from entire document) Lipton et al. do not teach the use of this compound in conjunction with a fungicide. However, the administration of the compound of Lipton even without the fungicide would inherently have the same effect in treating a fungal infection. The fungicide would be expected to have additive effects, but the methods of the claimed invention would still be achieved in the absence of the fungicide. It would also have been obvious to use antibiotics in combination with fungicide treatment to avoid or treat any secondary infections (page 1 of the specification).

6. Conclusion

A. No claim is allowable.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
September 04, 2003

ROBERT LANDSMAN
PATENT EXAMINER